

REMARKS

Claims 1–16 and 35 are cancelled.

Claims 17–34 and 36–42 are pending.

Claims 17–28 are withdrawn from consideration.

Amended Claims

Claims 17–34 and 36–42 are amended without prejudice or disclaimer of the subject matter claimed therein to recite a combination comprising a catheter and a nucleic acid comprising a gene encoding a single cyclin-dependent kinase inhibitor, wherein the cyclin-dependent kinase inhibitor is p27. No new matter is added in these amendments. The amendments are supported by the specification at page 12, lines 14–18, and at pages 7–14.

Priority

Applicants have amended the first line of the specification to include a statement indicating that the present application is a continuation of U.S. Serial No. 08/897,333, now U.S. Patent No. 6,177,272. Applicants have also cancelled claims 2–16 and submit that they have now supplied the clarification requested by the Examiner.

Double Patenting

Applicants enclose a Terminal Disclaimer in compliance with 37 C.R.F. §1.321(c) that disclaims the term of the patent that will issue from this patent application that

extends beyond the term of U.S. Patent No. 6,177,272. Applicants request that the Examiner withdraw the above obviousness-type double patenting rejection.

Claim Rejections – 35 U.S.C. §112, first paragraph

Claims 29-34 and 36-42 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way so as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. The Examiner alleges that the term “gene” comprises both transcribed and non-transcribed regions and that the specification does not disclose relevant identifying characteristics sufficient to describe the non-transcribed regions.

Applicants respectfully traverse the Examiner’s rejection. Applicants submit that the term “gene”, as used in the specification, describes a DNA sequence that encodes a transcribed region. For example, on page 10 at lines 7-9, genes are described as being under the control of regulatory elements. Also, on page 10 at lines 19-20, the specification discusses expressing the p27 gene via an expression vector. Accordingly, the specification defines gene in a manner that is clear and unambiguous to those skilled in the art..

Applicants submit that this 35 U.S.C. §112, first paragraph, rejection is overcome by the above arguments and respectfully request that the Examiner withdraw this rejection.

Claims 29-34 and 36-42 are rejected under 35 U.S.C. §112, first paragraph, because the Examiner alleges that no support is provided in the original claims or specification for the term “kit”. The Examiner also alleges that the specification does not recite compositions that include catheters, so that “kit” claims cannot derive support from the recitations involving catheters, such as are found at Example 2.

However, the specification at page 12, lines 14-18 indicates that compositions of the present invention can be administered by catheter, and thus discloses a combination of a catheter and the various nucleic acids of the invention. Accordingly, Applicants have amended claims 17-34 and 36-42 to recite a combination comprising a catheter and a nucleic acid comprising a gene encoding a single cyclin-dependent kinase inhibitor, where the cyclin-dependent kinase inhibitor is p27. Applicants submit that these amendments overcome this 35 U.S.C. §112, first paragraph, rejection and respectfully request that the Examiner withdraw this rejection.

Claim Rejections – 35 U.S.C. §112, second paragraph

Claims 32, 33, and 36 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The Examiner indicated that there is insufficient antecedent basis for the term “the nucleic acid”. In view of the amendments to claim 29, Applicants submit that Examiner’s rejection is overcome and respectfully request that the Examiner withdraw the rejection.

Claim rejections - 35 U.S.C. §103

Claims 29, 31-34, and 36-41 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 96/25507 (“Seth”) in view of U.S. 5,863,904 (“Nabel A”).

The Applicants enclose a declaration pursuant to 37 C.F.R. §1.131 stating that they were in possession of the claimed invention before the publication date of Seth. Applicants also include herewith a statement indicating that the subject matter of the present application and of the Nabel A patent was, at the time the invention of the present application was made, owned by the Trustees of the University of Michigan or subject to an obligation to assign to the Trustees of the University of Michigan. Hence, the Nabel A patent is not available as prior art against the present application. Accordingly, this rejection is overcome. Withdrawal of the §103 rejection is requested for the reasons stated above.

Claims 29-34, and 36-41 are rejected under 35 USC § 103(a) as being unpatentable over Seth in view of Nabel A and further in view of US 5,328,470 (“Nabel B”).

Applicants have addressed Seth and the Nabel A patent above. The Nabel B reference does not make up for the deficiencies of Seth and Nabel A. Withdrawal of the §103 rejection is requested for the reasons stated above.

Claims 29-34, and 36-41 are rejected under 35 USC § 103(a) as being unpatentable Seth in view of Nabel A and US 5,328,470 (Nabel B”), and further in view of US 6,541,197 (“Link”).

Applicants have addressed Seth and the Nabel A and B patents above. The Link reference does not make up for the deficiencies of Seth, Nabel A and Nabel B.

Withdrawal of the §103 rejection is requested for the reasons stated above.

Conclusions

Applicants have overcome each of the Examiner's rejections. The application is therefore in condition for allowance and early notice to this effect is earnestly solicited.

If, for any reason, the Examiner is unable to allow the application on the next Office Action and feels that an interview would be helpful to resolve any remaining issues, he is respectfully requested to contact the undersigned attorney at (312) 321-4229.

Respectfully submitted,

Dated: August 8, 2003

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EVIDENCE TO ESTABLISH COMMON OWNERSHIP

The subject matter of the present application and the subject matter of United States Patent Number 5,863,904 were, at the time the invention of the present application was made, owned by the Trustees of the University of Michigan or subject to an obligation of assign to the Trustees of the University of Michigan.

Respectfully submitted,

Dated: August 8, 2003

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